IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CITY OF WORCESTER, Plaintiff, v. PURDUE PHARMA L.P, d/b/a PURDUE PHARMA (DELAWARE) LIMITED PARTNERSHIP; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; COLLEGIUM PHARMACEUTICAL, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; and INSYS THERAPEUTICS, INC., Manufacturer Defendants, -and- MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN DRUG CORPORATION, Distributor Defendants, -and- JOHN KAPOOR, Individual Defendant.	)	Case No. 4:18-cv-11958-TSH

OPPOSITION TO PLAINTIFF'S EMERGENCY MOTION TO REMAND AND MEMORANDUM OF LAW IN SUPPORT OF OPPOSITION

Defendants AmerisourceBergen Drug Corporation ("ABDC"), McKesson Corporation, and Cardinal Health, Inc. (collectively, "Distributor Defendants" or "Distributors") respectfully submit this Opposition to Plaintiff's Emergency Motion to Remand and Memorandum of Law in Support of their Opposition, stating as follows.

INTRODUCTION

ABDC removed this action because the City of Worcester ("Plaintiff") asserts claims that the Distributor Defendants breached legal duties arising under the federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.* (the "CSA"). After removal, the Judicial Panel on Multidistrict Litigation ("JPML") issued an order conditionally transferring this case to *In re: Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804-DAP (N.D. Ohio) (the "MDL" or "MDL 2804") for consolidated pretrial proceedings.

This Court need not and should not reach the merits of Plaintiff's Emergency Motion to Remand ("Pl. Mot.") (Doc. 22). Nor should it act, as Plaintiff urges, on an "emergency" basis. Instead, for the reasons set forth in the Distributors' Motion to Stay, filed herewith, this Court should defer consideration of Plaintiff's remand motion and allow the issue presented in that motion to be decided on a national basis, alongside almost identical claims brought by other plaintiffs across the country as part of the national opioid litigation in MDL 2804.

Were this Court to reach the merits of Plaintiff's remand motion, the Court should deny the motion. Federal question jurisdiction under 28 U.S.C. § 1331 is proper under the Supreme Court's four-part test set forth in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), and *Gunn v. Minton*, 568 U.S. 251 (2013). Under that test, "federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258; *see One & Ken Valley*

Hous. Grp. v. Me. State Hous. Auth., 716 F.3d 218, 224 (1st Cir. 2013); *R.I. Fishermen's All., Inc. v. R.I. Dep't of Envtl. Mgmt.*, 585 F.3d 42, 48 (1st Cir. 2009).

Here, all four factors are satisfied. *First*, Plaintiff's Complaint necessarily raises federal issues because Plaintiff bases its claims against the Distributor Defendants on alleged failures to report and halt "suspicious orders" for prescription opioids—a duty that arises out of the federal CSA. *Second*, the parties actually dispute the federal issues because they contest whether the Distributor Defendants violated the CSA. *Third*, the federal issues are substantial given the federal interest in uniform enforcement of the CSA's nationwide regulatory scheme and the federal government's asserted interest in the subject matter of this litigation. *Fourth*, federal jurisdiction will not upset any federal-state balance. For these reasons, the Court should deny Plaintiff's remand motion.

BACKGROUND

I. Plaintiff's Action

Plaintiff filed this lawsuit in Massachusetts Superior Court, County of Worcester, on July 30, 2018. The Complaint asserts claims against three groups of Defendants: (1) manufacturers, which make and promote opioid medications; (2) Distributors, which are pharmaceutical wholesale distributors; and (3) a physician who allegedly marketed or prescribed opioid medications. With respect to Distributor Defendants, Plaintiff complains of over-distribution of prescription opioids into Massachusetts and alleges that Distributor Defendants "flooded" the City of Worcester "with an excess supply of pharmaceutical opioids." Compl. ¶ 16. The Complaint asserts seven counts against ABDC and the other Distributor Defendants: public nuisance (Count I); common law fraud (Count II); negligent misrepresentation (Count III); negligence (Count IV); unfair and deceptive acts in violation of Mass. Gen. Laws ch. 93A, Section 11 (Count V); unjust enrichment (Count VI); and civil conspiracy (Count VII). *See*

Compl. ¶¶ 466-536, Prayer for Relief.

Plaintiff's central theory against Distributor Defendants is that they allegedly violated two duties "to report to [the Drug Enforcement Administration] suspicious orders for controlled substances and to take other precautions to ensure that those medications would not be diverted into illegal channels," Compl. ¶ 15 (internal quotations omitted), and that Distributor Defendants failed to "detect, report, inspect, and halt suspicious orders, so as to prevent the black market diversions of controlled substances," *id.* ¶ 16. The two alleged duties on which Plaintiff's claims rest arise out of the federal CSA and its implementing regulations. The alleged reporting duty—*i.e.*, to implement effective controls to detect and report suspicious orders—is set forth in the CSA's implementing regulations. *See* 21 C.F.R. § 1301.74(b). The alleged shipment-halting duty arises out of the Drug Enforcement Administration's ("DEA") interpretation of the CSA, pursuant to which Distributors must "decline to ship" suspicious orders for controlled substances. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212-13 (D.C. Cir. 2017).

Plaintiff thus relies on federal law to establish the alleged duties to report and halt shipments of suspicious orders for controlled substances. *See, e.g.*, Compl. ¶ 15 (citing 21 C.F.R. § 1301.71(a) to establish Distributor Defendants alleged "duties to report to the DEA suspicious orders for controlled substances" (quotation marks and alterations omitted)); *id.* ¶ 348 ("Under the statutory scheme set out in the CSA, enacted by Congress in 1970, wholesale pharmaceutical distributors were given the statutory obligation to have in place 'effective controls' to prevent the 'diversion' of controlled substances. 21 C.F.R. §1301.71(a)."). Although Plaintiff purports to disavow stating a federal question, Massachusetts law does not impose an independent duty on wholesale distributors to report or halt shipments of suspicious orders for prescription opioids.

II. The Multidistrict Litigation

Plaintiff's claims are the same as those being asserted in federal court by more than a thousand other municipalities and other plaintiffs. To consolidate these cases for coordinated pre-trial proceedings, the JPML formed an MDL in the Northern District of Ohio. In total, more than a thousand actions are now pending in the MDL. As new cases are filed across the country each week, the JPML continues—and will continue—to transfer more actions to the MDL. On September 26, 2018, the JPML issued an order conditionally transferring this case to the MDL on the ground that it appears to "involve questions of fact that are common to the actions previously transferred to the Northern District of Ohio and assigned to Judge Polster." Conditional Transfer Order (CTO-57), attached as Ex. D to Decl. of Judith Scolnick, dated Oct. 4, 2018 ("Scolnick Decl."; Doc. 22-5). The JPML will likely make a final decision regarding transfer shortly after November 29, 2018.[1] The Distributor Defendants are, accordingly, filing a contemporaneous motion to stay this action while the JPML makes its determination.

To the extent that the Court reaches the merits of Plaintiff's motion to remand, however, that motion should be denied for the reasons set forth in the Notice of Removal and below.

ARGUMENT

I. The Court Should Not Rule on Plaintiff's Remand Motion on an Emergency Basis, But, Rather, Should Stay this Action

The Court need not, and should not, reach the merits of Plaintiff's remand motion or act on an emergency basis, but rather, should defer consideration of Plaintiff's remand motion and allow the issue presented in that motion to be decided on a national basis, alongside almost identical claims brought by other plaintiffs across the country as part of the national opioid litigation in MDL 2804. This action by City of Worcester is one of hundreds of related lawsuits

[1] *See* http://www.jpml.uscourts.gov/hearing-information.

asserting claims against manufacturers, distributors, pharmacies, and physicians arising out of the sale, marketing, and distribution of prescription opioid medications. Concurrently with the start of proceedings in this Court, the JPML will be deciding whether to transfer this action to a multidistrict litigation pending before Judge Dan Polster in the MDL, where the case would join more than a thousand other opioid-related actions involving common factual allegations, common legal issues, and common defendants.

For these reasons, set forth more fully in the accompanying Motion to Stay, the Court should defer consideration of Plaintiff's remand motion until the JPML makes a final transfer decision. Were the Court to consider Plaintiff's remand motion, however, the motion should be denied.

II. Plaintiff's Complaint Contains a Question of Federal Law

Remand would be inappropriate in this case because the Complaint presents questions of federal law. Federal courts have removal jurisdiction over "any civil action brought in a State court of which the district courts of the United States have original jurisdiction," 28 U.S.C. § 1441(a), and original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States," 28 U.S.C. § 1331. "A single claim over which federal-question jurisdiction exists is sufficient to allow removal." *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194 (2d Cir. 2005); *see Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 563 (2005).

Even where state law creates the causes of action asserted in a complaint, one or more of those causes of action may raise a federal question sufficient to warrant removal jurisdiction under the Supreme Court's *Grable* and *Gunn* decisions. *See Gunn*, 568 U.S. at 258; *Grable*, 545 U.S. at 315. Given Plaintiff's reliance on duties arising under federal law, all four of the requirements for federal jurisdiction—a federal issue that is (1) necessarily raised, (2) actually

disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance—are satisfied.[2] Therefore, this Court has jurisdiction.

A. The Complaint "necessarily raises" a federal issue

Plaintiff's state law claims "necessarily raise" a federal question because its "asserted right to relief under state law requires resolution of a federal question." *R.I. Fishermen's Alliance*, 585 F.3d at 49. Significantly, "an action under 28 U.S.C. § 1331(a) arises . . . *if the action requires construction of a federal statute*, or at least a distinctive policy of a federal statute requires the application of federal legal principles." *V.I. Hous. Auth. v. Coastal Gen. Constr. Servs. Corp.*, 27 F.3d 911, 916 (3d Cir. 1994) (emphasis added); *see Merrell Dow Pharms. v. Thompson*, 478 U.S. 804, 808-09 (1986) (federal question jurisdiction exists if "vindication of a right under state law *necessarily turn*[*s*] *on some construction of federal law*" (emphasis added, internal citation omitted)).

In determining whether state law claims turn on construction or application of federal law, the Court must "begin by considering the duty underlying each claim." *NASDAQ*, 770 F.3d at 1020. "A state-law claim 'necessarily' raises federal questions where the claim is affirmatively 'premised' on a violation of federal law," *Jacobson*, 824 F.3d at 315, or where the "singular duty" underlying the claim arises under federal law, *NASDAQ*, 770 F.3d at 1021. Here, Plaintiff's claims necessarily raise federal issues because they are premised on Distributors'

[2] Courts have found these factors to be satisfied in cases where state law claims are predicated on violations of federal statutes governing complex, nationwide regulatory schemes for which uniformity is essential. *See, e.g.*, *New York ex rel. Jacobson v. Wells Fargo Nat'l Bank, NA*, 824 F.3d 308, 315-18 (2d Cir. 2016) (state law claims based on alleged violation of Internal Revenue Code satisfy *Grable*); *NASDAQ OMX Grp., Inc. v. UBS Sec., LLC*, 770 F.3d 1010, 1031 (2d Cir. 2014) (state law claims premised on violations of Exchange Act "necessarily raise disputed issues of federal law of significant interest to the federal system as a whole"); *Broder*, 418 F.3d at 196 (state law claims premised on alleged violations of Communication Act satisfy "*Grable* test for federal-question removal jurisdiction"); *Ranck v. Mt. Hood Cable Regulatory Comm'n*, No. 3:16-cv-02409-AA, 2017 WL 1752954, at *5 (D. Or. May 2, 2017).

alleged violations of legal duties—*i.e.*, the duties to report and halt suspicious orders for controlled substances—that arise out of the CSA and its implementing regulations. *See* 21 C.F.R. § 1301.74(b); *Masters Pharm*, 861 F.3d at 212-13.

Despite its protestations to the contrary, Plaintiff's reliance on federal law is evident on the face of its Complaint. *See Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987) (federal jurisdiction exists when federal question is presented "on the face of the plaintiffs' properly pleaded complaint"). Throughout the Complaint, Plaintiff cites federal laws and regulations to establish the duties to report and halt suspicious orders, and repeatedly alleges that Distributors' violations of these duties give rise to Plaintiff's causes of action. *See, e.g.*, Compl. ¶ 15 (citing *Masters Pharm.*, 861 F.3d at 211-12 to establish Distributor Defendants' alleged duties "to ensure that [opioid] medications would not be diverted into illegal channels"); *id.* ¶ 17 (alleging investigations and fines by DEA for allegedly "failing to: (a) operate its mandatory internal oversight system in good faith; (b) report suspicious orders to the DEA; and (c) halt the shipment of 'suspicious orders for controlled substances' when they were discovered."); *id.* ¶ 348 (alleging that, under the CSA "the wholesaler must investigate the suspicious order, document the result of the investigation, and, if not reasonably satisfied that the suspicious order is for the legitimate sale of the Retail End User, it must immediately halt the sale" (citing *Masters Pharm.*, 861 F.3d at 212-13)); *id.* ¶ 503 (alleging that "the FCSA [Federal Controlled Substances Act]. . . create[s] statutory standards that require prescription drug distributors to maintain and monitor a closed chain of distribution and detect, report, inspect, and halt suspicious orders, so as to prevent the black market diversion of controlled substances.").

As these and other citations demonstrate, Plaintiff's claims against Distributor Defendants rest squarely on its allegations that they breached duties arising out of the CSA and its implementing regulations. Plaintiff asserts that Distributor Defendants have "identical" duties

under Massachusetts law, but, notably, points to no supporting authority. Compl. ¶ 349. Indeed, Plaintiff fails to cite any specific provision of state law that imposes a requirement that wholesale pharmaceutical distributors identify and report suspicious orders of controlled substances to a Massachusetts government official or entity, or a state law source for a requirement that wholesale pharmaceutical distributors halt suspicious orders of controlled substances from registered pharmacies.

To the contrary, the Massachusetts laws that Plaintiff cites require only that wholesale distributors comply with federal laws and regulations governing the distribution of controlled substances. Plaintiff cites four provisions of state law that it claims gives rise to duties to report and halt shipments of suspicious orders: (i) Mass. Gen. Laws Ann. ch. 94C, § 12(a), which merely sets forth the prerequisites for the issuance of a registration to manufacture or distribute controlled substances; (ii) 105 CMR 700.006(A), which provides only that "[e]very person registered with the Commissioner shall keep records, maintain inventories, and make reports in conformance with the requirements of the Federal Comprehensive Drug Prevention and Control Act of 1970 and the Federal Food, Drug and Cosmetic Act, and 105 CMR 700.006[]"; (iii) 247 CMR 7.04(9)(a), which provides that "[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations"; and (iv) 247 CMR 7.04(9)(b), which merely provides that "[w]holesale drug distributors shall permit the agents of the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law." *See* Compl. ¶ 16. None of these provisions creates duties to report and halt shipments of suspicious orders.

Plaintiff's claim of negligence *per se* illustrates this point, as Plaintiff alleges that Distributor Defendants' "conduct relating to the wholesale distribution of controlled substances

is governed by," among other things, "the federal Controlled Substances Act," that the CSA "create[s] statutory standards that require prescription drug distributors to maintain and monitor a closed chain of distribution, and to detect, report, inspect, and halt suspicious orders so as to prevent the black market diversion of controlled substances," and that Distributor Defendants' alleged "violations of the statutory standards set forth in . . . the FCSA constitute negligence under Massachusetts law." Compl. ¶¶ 502, 503, 507 (Count II). The alleged duty to prevent or halt shipments of suspicious orders arises *solely* under the federal CSA, and *not* under state law. "Thus, it is not logically possible for the plaintiffs to prevail on this cause of action without affirmatively answering the embedded question of whether federal law" required Distributor Defendants to report and halt shipments of suspicious orders for prescription opioids under the circumstances. *Rhode Island Fishermen's All.*, 585 F.3d at 49. "That is enough to make out a federal question." *Id.*

Although a plaintiff "may avoid federal jurisdiction by *exclusive* reliance on state law," *Caterpillar*, 482 U.S. at 392 (emphasis added), Plaintiff's claims here have no such exclusive state law basis. As noted, contrary to Plaintiff's assertions that "[t]he Distributor Defendants have identical statutory obligations [to those under the CSA] arising under Massachusetts state law," *id.* ¶ 349, Plaintiff's identify no such statutory obligations of Distributors under state law to report, or stop, suspicious orders for controlled substances. For this reason, the six opioid cases upon which Plaintiff relies in urging this Court to remand this action are unavailing. *See* Pl. Mot. (Doc. 22) at 2, 10. Five of the six opioid cases cited by Plaintiff involve claims alleging violations of state laws that impose duties on distributors, such as requirements to report prescription drug diversions to state regulatory bodies. *See Uintah County, Utah v. Purdue Pharma, L.P.*, No. 2:18-cv-585-RJS, 2018 WL 3747847, at *1 (D. Utah Aug. 7, 2018) (alleging, among other things, violation of duty to report suspicious opioid orders to "the Utah Department

of Health") (quoting complaint); *Weber County, Utah v. Purdue Pharma, L.P.*, No. 1:18-cv-00089-RJS, 2018 WL 3747846, at *1 (D. Utah Aug. 7, 2018) (same); *New Mexico v. Purdue Pharma L.P.*, 323 F. Supp. 3d 1242, 1251 (D.N.M. 2018)[3] (allegations by State Attorney General of violations of state regulations requiring distributors to report prescription drug diversions to the New Mexico Board of Pharmacy, as well as to adopt measures to prevent diversion); *Delaware ex rel. Denn v. Purdue Pharma L.P.*, No. 1:18-cv-383, 2018 WL 1942363, at *3 (D. Del. Apr. 25, 2018) (allegations by State Attorney General of violations of Delaware Controlled Substances Act, which requires "distributors to maintain 'effective controls against diversion [into illegitimate] channels'") (quoting 16 Del. C. § 4735(b)(1)–(2)); Mem. Op. & Order, *West Virginia ex rel. Morrisey v. McKesson Corp.*, No. 2:17-cv-3555 (S.D. W. Va. Feb. 15, 2018) (Scolnick Decl. Ex. B) (alleging multiple violations of the West Virginia Uniform Controlled Substances Act). The remand order in the sixth opioid case upon which Plaintiff relies is likewise of no assistance to it here because the removing party in that action had stipulated that it would not remove the action based on the original petition, and further, unlike Distributor Defendants here, did "not assert that resolution of a substantial question of federal law is necessary in relation to an essential element of plaintiff's state law claims." Order, *Oklahoma ex rel. Mike Hunter v. Purdue Pharma, L.P.*, No. 18-cv-574-M (D. Okla. Aug. 3, 2018) (Scolnick Decl. Ex. C, Doc. 22-4), at 9 n.4.

By contrast, Plaintiff's claims here rely on alleged violations of duties arising solely from the federal CSA, and Plaintiff cannot locate parallel state-law statutory requirements to support its allegations against Distributor Defendants. Significantly, in its remand motion, Plaintiff does not dispute that it predicates its claims on allegations that Distributors breached duties arising

[3] The citation furnished by Plaintiff is No. 1:18-cv-00386, 2018 WL 2943246, at *5 (D.N.M. June 12, 2018).

under the CSA. To the contrary, Plaintiff doubles down on its invocation of federal law, arguing that Distributor Defendants' alleged "wrongdoing . . . goes beyond their mere failure to comply with specific obligations to 'identify, report, and then not ship' suspicious orders, as specifically prescribed by the CSA." Pl. Mot. at 11. But, again, Plaintiff cites no applicable state law. Plaintiff may not repeatedly allege violations of federal law and then argue that it has not raised a federal question.

In short, Plaintiff has not identified and cannot identify any state law duty that could support its claims that Distributors over-distributed controlled substances into Massachusetts. Plaintiff's purported state law causes of action hinge on its allegations that Distributors breached duties arising out of the CSA and its implementing regulations. To determine whether Distributors breached those duties, a court would necessarily have to interpret and apply the CSA. Plaintiff's claims therefore necessarily raise federal issues.

B. The parties "actually dispute" the federal issue

The federal issues raised by the Complaint are "actually disputed" because the parties contest whether the CSA and its implementing regulations in fact give rise to duties to report and halt suspicious orders for prescription opioids, the scope and contours of any such duties under the CSA, and whether Distributors violated these alleged duties. Because Plaintiff's claims against Distributors depend on their theory that Distributors breached these alleged duties, this issue is the "central point of dispute." *Gunn*, 568 U.S. at 259.

In assessing whether Distributors breached duties arising out of the CSA, the Court must examine "the contours of [the] federal duty," "the scope of that duty," and "whether [Distributors' conduct] amounted to a breach of that duty." *NASDAQ*, 770 F.3d. at 1023. This inquiry will require the Court to determine, among other disputes, (1) whether the CSA and its implementing regulations in fact give rise to the duties to report and halt suspicious orders, (2)

what any such duties entail, (3) what constitutes a "suspicious" delivery under the CSA's implementing regulations, (4) what actions should have been taken to resolve those suspicions or "halt" the shipment, and (5) whether existing processes satisfy federal reporting guidelines.

Given these disputes, Plaintiff cannot credibly maintain that the federal issue is not "actually disputed." Distributors deny that they violated their duties under the CSA in the manner alleged in Plaintiff's Complaint. Plaintiff's allegations that Distributor Defendants were investigated and fined by DEA for allegedly "failing to: (a) operate its mandatory internal oversight system in good faith; (b) report suspicious orders to the DEA; and (c) halt the shipment of 'suspicious orders for controlled substances' when they were discovered[,]" Comp. ¶ 17, are a red herring. Even if prior settlements with other government entities related to *other jurisdictions* were relevant to this matter (they are not), those settlements would not establish that Distributors have conceded liability to Plaintiff. Thus, the parties actually dispute whether Distributors violated the CSA by allegedly failing to report and stop suspicious orders.

C. The federal issues are "substantial."

The substantiality inquiry looks "to the importance of the issue to the federal system as a whole." *Gunn*, 568 U.S. at 260, 261-62; *see R.I. Fishermen's All.*, 585 F.3d at 51; *Massachusetts v. Wampanoag Tribe of Gay Head*, 36 F.Supp.3d 229, 234 (D. Mass. 2014). A federal issue "can be important for many reasons," including because (1) "state adjudication would undermine the development of a uniform body of federal law"; (2) "resolution of the issue has broad significance for the federal government"; or (3) "the case presents a nearly pure issue of law that would have applications to other federal cases." *Bd. of Commissioners of Se. La. Flood Prot. Auth.-E. v. Tennessee Gas Pipeline Co.*, 850 F.3d 714, 724 (5th Cir. 2017) (alterations and quotation marks omitted). Exercising federal question jurisdiction in such cases "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state

law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable*, 545 U.S. at 312. That common-sense notion applies here.

1. There is a federal interest in interpreting the CSA uniformly

The federal issues presented here are important because there is a "substantial federal interest" in ensuring "uniformity of interpretation" of the CSA. *R.I. Fishermen's All.*, 585 F.3d at 51. Courts have often found federal issues to be sufficiently substantial where they raise "questions [that] involve aspects of . . . complex federal regulatory scheme[s] . . . as to which there is a serious federal interest in claiming the advantages thought to be inherent in a federal forum." *Broder*, 418 F.3d at 195 (quotation marks omitted).

In *R.I. Fishermen's Alliance*, for example, the First Circuit found that there was a significant federal interest in ensuring that states comply with a federally-sanctioned interstate fishery management plan, and that such compacts are uniformly interpreted. 585 F.3d at 51. In *NASDAQ*, the Second Circuit similarly ruled that "the disputed federal issue in th[e] case—whether [the defendant] violated its Exchange Act obligation to provide a fair and orderly market in conducting an IPO—is sufficiently significant to the development of a uniform body of federal securities regulation to satisfy the requirement of importance to the federal system as a whole." 770 F.3d at 1024 (quotation marks omitted). Likewise, in *Jacobson*, the Second Circuit held that "minimizing uncertainty over the tax treatment of mortgage-backed securities, as Congress intended, fully justif[ied] resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." 824 F.3d at 318.

Similarly, Plaintiff's claims implicate uniformity concerns because they would require this Court to determine the existence and scope of Distributors' obligations under the CSA and whether Distributors breached those duties. In enacting the CSA, Congress stated that it was

"providing the legitimate drug industry with a *unified* approach to narcotic and dangerous drug control." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572 (emphasis added). To this end, Congress declared that while the CSA does not occupy the field of controlled substances regulation, state law on controlled substances cannot create a "positive conflict" with the CSA. 21 U.S.C. § 903. Thus, the legislative history and the text of the CSA state a substantial federal interest in consistent, nationwide regulation of controlled substances distribution. Plaintiff's claims "involve aspects of the complex federal regulatory scheme applicable to" the national prescription drug supply chain. *Broder*, 418 F.3d at 195. They are thus "sufficiently significant to the development of a uniform body of [controlled substances] regulation to satisfy the requirement of importance to the federal system as a whole." *NASDAQ*, 770 F.3d at 1024.

Furthermore, "minimizing uncertainty over" reporting and shipping obligations under the CSA "justifies resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Jacobson*, 824 F.3d at 317-18 (quotation marks and alteration omitted). "Given that . . . plaintiff['s] claims turn on the interpretation of the federal regulations governing" controlled substances and also given "the importance of those regulations to the Congressional scheme, this case plainly falls within the narrow swath of cases described in *Grable*." *Anversa v. Partners Healthcare Sys., Inc.*, 835 F.3d 167, 174 n.5 (1st Cir. 2016).

It should thus be left to federal courts—here, a single MDL—to interpret the CSA.

2. The federal issues presented in this case have broad significance

The scope of the obligations the CSA places on distributors of pharmaceuticals has broad significance to the federal government, including by affecting the DEA's ability to enforce the CSA. The federal government itself has already made clear the effect that the opioid litigation will have on its ability to enforce the CSA. Most notably, the Department of Justice has filed a

Statement of Interest on behalf of the United States in the MDL proceedings, asserting the federal government's interests in, among other things, its "law enforcement and legal activities in conjunction . . . with the multidistrict litigation," specifically including "[c]riminal and civil tools available under the Controlled Substances Act." *In re: Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804 (N.D. Ohio Mar. 1, 2018), ECF No. 161, at 7.

Allowing a state court to resolve state law claims premised on violations of the CSA—and to determine the existence and scope of any duties under the CSA—creates the potential for inconsistent interpretations of the CSA across jurisdictions. *See* 21 U.S.C. § 903 (although Congress did not intend to "occupy the field" of controlled substances regulation with CSA, CSA pre-empts inconsistent state law). Conflicting interpretations of the CSA issued by state courts would inevitably undermine the federal government's efforts to enforce the statute and sow confusion among federally regulated entities.

3. This case presents a nearly pure issue of law that would have applications to other federal cases

As noted, this case would require a court to determine the existence of duties arising under the CSA, the scope and contour of any such duties that exist, and "whether [Distributors' conduct] amounted to a breach of that duty." *NASDAQ*, 770 F.3d. at 1023. These questions present "nearly pure issue[s] of law" that would necessarily have applications to other federal cases. *One & Ken Valley Hous. Grp.*, 716 F.3d at 225. Indeed, these issues apply to the more than one thousand actions pending in the MDL. Moreover, the resolution of this legal issue will apply broadly to all cases in which a plaintiff alleges that any distributor of pharmaceuticals breached its alleged duties to report or halt shipments of suspicious orders.

D. Federal jurisdiction will not disrupt the Congressionally-approved balance of federal-state judicial responsibilities.

Finally, the federal issues presented by Plaintiff's Complaint are capable of resolution in

federal court "without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258. Federal courts exclusively hear challenges to DEA authority to enforce the federal CSA against distributors.[4] Similarly, federal courts have exclusive jurisdiction over proceedings seeking to enjoin violations of the CSA. *See* 21 U.S.C. § 882(a). Thus, federal courts already are the exclusive forum for determining the permissible scope of restraints on Distributors under the federal CSA. Furthermore, as explained above, allowing cases like this one to proceed in federal court promotes uniform development of federal law. By contrast, litigating this case in state court runs the risk of the state court applying federal requirements inconsistently with the manner in which DEA—the federal agency responsible for enforcing the CSA—applies them.

This case does not implicate any comparably important state law issues. This Court would be required to apply well-settled state tort law only *after* it resolves the federal question regarding the Distributors' obligations under the CSA. This Court will not be usurping any state judicial responsibilities in this case.

E. A federal cause of action is not essential to jurisdiction

Plaintiff incorrectly argues that the lack of a federal cause of action renders federal jurisdiction lacking. Pl. Mot. 14-15. That argument is inconsistent with *Grable*. In *Grable*, the Supreme Court specifically held that lack of a federal cause of action does *not* foreclose federal-question jurisdiction. *See Broder*, 418 F.3d at 196; *In re Pharm. Indus. Average Wholesale Price Litig.*, 457 F.Supp.2d 77, 80 (D. Mass. 2006) ("It is now clear under *Grable* that the lack of a private federal cause of action does not preclude jurisdiction."). Thus, the fact that the CSA does

[4] *See, e.g.*, *PDK Labs. Inc. v. U.S. Drug Enf't Admin.*, 362 F.3d 786 (D.C. Cir. 2004) (challenge to DEA program enforcing CSA to prevent diversion of ephedrine); *Admin. Subpoena Walgreen Co. v. U.S. Drug Enf't Admin.*, 913 F.Supp.2d 243 (E.D. Va. 2012) (resolving motion to require DEA to return subpoenaed documents); *Cardinal Health, Inc. v. Holder*, 846 F.Supp.2d 203 (D.D.C. 2012) (challenge under Administrative Procedure Act to DEA order suspending registration of distribution facility).

not afford Plaintiff a private right of action does not diminish the federal questions here.

For the foregoing reasons, and those set forth in the Notice of Removal, were the Court to reach the merits of Plaintiff's remand motion, the motion should be denied.

CONCLUSION

For the reasons set forth above, Defendants respectfully request the Court defer consideration of Plaintiff's remand motion until the JPML makes a final transfer decision or, in the alternative, deny Plaintiff's motion for remand.

WHEREFORE, Defendants respectfully request that this Honorable Court:

A. Defer consideration of Plaintiff's Motion to Remand (Doc. 22) until the JPML makes a final transfer decision or, *in the alternative*,

B. Deny Plaintiff's Motion to Remand in its entirety; and

C. Grant such other and further relief as justice may require.

Respectfully submitted,

October 18, 2018

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Certificate of Service

I hereby certify that on October 18, 2018, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of this filing to all counsel of record.

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